In re Application of: MALONEK et al.
Serial No.: 09/849,637
Filed: May 4, 2001
Office Action Mailing Date: July 9, 2007

Examiner: G.R. Evanisko
Group Art Unit: 3762
Attorney Docket: IMP031.228776

In the Claims:

1 - 4 (Canceled)

5. (Withdrawn) A lead according to Claim 70, wherein said lead comprises two pairs of electrodes, each of said pairs comprising a sensing electrode and a signal delivery electrode, wherein the sensing electrode of one of said pairs of electrodes is in adjacent axial arrangement with respect to the sensing electrode of the other pair of electrodes.

6. (Withdrawn) A lead according to claim 5, wherein each sensing electrode is spaced from the nearest disposed signal delivery electrodes by a distance such as to minimize interference between the signal provided by said sensing electrode and the field provided by said nearest signal delivery electrodes, and such that each said nearest signal delivery electrode provides an electric field that corresponds with said signal provided by the corresponding said sensing electrode.

7. (Withdrawn) A lead according to claim 6, wherein the distance is between about 2 mm and about 10 mm.

8. (Withdrawn) A lead according to claim 5, wherein each sensing electrode comprises a substantially cylindrical member having an external diameter and having a lumen of a diameter slightly larger than the outer diameter of the distal portion of said lead.

9. (Withdrawn) A lead according to claim 8, wherein the cylindrical member comprises a longitudinal length less than the external diameter thereof.

10. (Withdrawn) A lead according to claim 9, wherein the external diameter is less than 1.2 mm.

11. (Withdrawn) A lead according to claim 70, wherein each sensing electrode is adapted for sensing tissue impedance, pressure, tension or electrical signal.

12. (Withdrawn) A lead according to claim 70, wherein each sensing electrode means comprises a sensing electrode made from a material selected from the group consisting of titanium coated with iridium oxide; titanium coated with titanium nitride; platinum iridium coated with iridium oxide; platinum iridium coated with titanium nitride; platinum iridium coated with sintered platinum; titanium; platinum iridium; pyrolitic carbon; and any other conductive material approved for chronic use in the body.

13. (Withdrawn) A lead according to claim 70, wherein each signal delivery electrode is comprised of one or more electrical conducting elements wound in parallel to a spiral coil-like form having an external diameter and having a lumen of a diameter slightly larger than the outer diameter of the distal portion of said lead.

14. (Withdrawn) A lead according to claim 13, wherein the external diameter is less than 1.2 mm.

15. (Withdrawn) A lead according to claim 13, wherein the spiral coil-like form comprises a longitudinal length substantially greater than the external diameter thereof.

16. (Withdrawn) A lead according to claim 15, wherein the longitudinal length is between about 5 mm and about 40 mm.

17. (Withdrawn) A lead as claimed in claim 13, wherein the spiral coil-like form comprises an effective external surface area of between about 30 square mm and about 250 square mm.

18. (Withdrawn) A lead according to claim 70, wherein each signal delivery electrode means comprises a signal delivery electrode having impedance in the range of between about 50 ohms and about 500 ohms.

19. (Previously Presented) A lead according to claim 43, wherein the at least one signal delivery electrode is made from a material selected from titanium coated with iridium oxide.

20. (Withdrawn) A lead as claimed in claim 5, wherein the electrodes are spaced along the lead such as to occupy a lead length of between about 20 mm and about 150 mm.

21. (Withdrawn) A lead according to claim 5, wherein each electrode of the two pairs of electrodes comprises at least one suitable conductor having suitable distal connector means and proximal connector means for operatively connecting each corresponding said electrode to said connection means, respectively.

22. (Withdrawn) A lead according to claim 21, wherein the electrodes are carried on a terminal support tube comprised on the distal portion of said lead, said terminal support tube comprising a substantially tubular flexible body member comprising a plurality of longitudinal channels, each said channel adapted to accommodate at least one conductor corresponding to one of said electrodes, said

channels terminating at a corresponding distal terminal area adapted for accommodating a corresponding distal connector means.

23. (Withdrawn) A lead according to claim 22, wherein the distal connector means for each electrode comprises a substantially flat terminal member having an exposed surface substantially larger in area than the transverse cross-sectional area of the corresponding at least one conductor, said distal connector means being adapted for electrically joining thereto the distal end of said corresponding at least one conductor, and said exposed surface adapted for electrically joining thereto a corresponding one of said electrodes.

24. (Withdrawn) A lead according to claim 23, wherein a laser weld is used to electrically join each one of the electrodes to the exposed surface of a corresponding one of the distal connector means.

25. (Withdrawn) A lead according to claim 22, wherein each one of the distal connector means is electrically connected to the distal end of a corresponding one of the at least one conductor by inserting said distal end of said conductor into a well provided on said distal connector means.

26. (Withdrawn) A lead according to claim 23, wherein the flat terminal member is made from titanium.

27. (Withdrawn) A lead according to claim 22, wherein the lead comprises a proximal portion joined to the distal portion thereof, wherein said proximal portion comprises a flexible tubular member having a lumen, a proximal portion of the conductors being carried in said lumen in coiled spiral configuration.

28. (Withdrawn) A lead according to claim 70, wherein the connection means for connecting the proximal end to the controller comprises at least one implantable connector.

29. (Withdrawn) A lead according to claim 70, further comprising an ogival intrusion head and a length of suitable tubing, said ogival intrusion head being proximally joined to the distal portion of said lead via said length of suitable tubing.

30. (Withdrawn) A lead according to claim 29, wherein the tubing comprises a bend.

31. (Withdrawn) A lead according to claim 30, wherein the bend comprises an angle of between 30° and about 90°, when unstressed.

32. (Withdrawn) A lead as claimed in claim 70, further comprising means for introducing and implanting at least the distal portion of said lead within the at least portion of tissue.

33. (Withdrawn) A lead according to claim 70, comprising an external diameter such as to enable said lead to be inserted into a suitable blood vessel having a lumen of diameter less than about 1.5mm.

34-35. (Canceled)

36. (Withdrawn) A lead according to claim 70, wherein the control means comprises means for applying to the delivery electrodes a voltage and/or current required for performing an operation chosen from among providing non-excitatory stimuli to the heart or performing pacing or performing defibrillation.

In re Application of: MALONEK et al.
Serial No.: 09/849,637
Filed: May 4, 2001
Office Action Mailing Date: July 9, 2007

Examiner: G.R. Evanisko
Group Art Unit: 3762
Attorney Docket: IMP031.228776

37. (Withdrawn) A lead according to claim 70, wherein the control means comprises means for generating a non-excitatory electric field having suitable parameters such as to provide the desired change in the activity of the tissue or part thereof.

38. (Withdrawn) A lead as claimed in claim 70, wherein the location of each electrode relative to the anatomical boundary between the atrium and the ventricle of the heart is identified by using said electrode.

39. (Withdrawn) A lead as claimed in claim 70, wherein the location of each electrode relative to the anatomical boundary between different heart chambers is identified by using said electrode.

40. (Withdrawn) A lead as claimed in claim 70, wherein the control means is characterized in being adapted for either selectively enabling a suitable non-excitatory electric field to be generated by the delivery electrode means such as to provide the desired modification in the activity of the portion of tissue or selectively not generating an electric field, wherein said electric field is either generated or not generated depending on at least one characterizing feature of the signal previously provided by the sensing electrode means.

41. (Previously Presented) A lead as claimed in claim 43, wherein at least one of the at least one signal delivery electrodes is a unitary electrode also adapted for sensing activity of said at least portion of a tissue and providing a signal characteristic of said activity.

42. (Canceled)

In re Application of: MALONEK et al.
Serial No.: 09/849,637
Filed: May 4, 2001
Office Action Mailing Date: July 9, 2007

Examiner: G.R. Evanisko
Group Art Unit: 3762
Attorney Docket: IMP031.228776

43. (Currently Amended) A lead for modifying the activity of at least a portion of a tissue, said lead comprising:

at least one signal delivery electrode in the form of a flexible circumferential element positioned around the lead, having a diameter less than 1.5 mm, and having capacitance greater than 300 microfarads and less than 3000 microfarads, wherein the electrode is ~~and~~ adapted to withstand chronic delivery to said at least portion of tissue a non-excitatory electric field having an amplitude and duration suitable to modify the contractility of a human cardiac muscle when applied during a refractory period of said muscle; and

~~connection means operatively connected to~~ a connector adapted to connect to said at least one signal delivery electrode for enabling said at least one signal delivery electrode to be operatively connected to control ~~means~~circuitry.

44. (Currently Amended) A lead as claimed in claim 43, wherein the control ~~means~~ circuitry is characterized in being adapted for either selectively enabling a non-excitatory electric field to be generated by said at least one signal delivery electrode such as to modify the contractility of a human cardiac muscle when applied during a refractory period of said muscle or for selectively not generating an electric field wherein said electric field is either generated or not generated according to at least one characterizing feature of the signal previously provided by the same or another one of said at least one sensing electrode.

45. (Withdrawn) A lead according to any proceeding claim, wherein the tissue to be modified by said lead is tissue of a human heart or part thereof.

46. (Withdrawn) A lead according to claim 45, optionally for performing pacing of said heart.

47. (Withdrawn) A lead according to claim 45, optionally for performing defibrillation of said heart.

48. (Withdrawn) A lead according to any one of claims 1 to 44 and 46 to 47, wherein said lead is implanted into a vessel or body cavity using any suitable implantation method.

49. (Canceled)

50. (Withdrawn) A method for applying non-excitatory stimuli to the heart and optionally performing pacing and defibrillation thereof, comprising providing a lead as claimed in any one of claims 1 to 44 and 46 to 47, and positioning said distal portion of the lead within a blood vessel of said heart or portion thereof.

51. (Withdrawn) A method for applying non-excitatory stimuli to said tissue, comprising providing a lead as claimed in any one of claims 1 to 44 and 46 to 47, and positioning said distal portion of the lead within a blood vessel of said tissue or portion thereof.

52. (Withdrawn) A method according to claim 51, wherein said tissue is a body organ.

53. (Withdrawn) A method according to claim 51, wherein said tissue is a body cavity.

54. (Withdrawn) A method according to claim 53, wherein said body cavity is the heart.

55. (Withdrawn) A method according to claim 53, wherein said body cavity is a blood vessel.

56. (Withdrawn) A method according to claim 53, wherein said body cavity is selected from among the urinary bladder, the gastro-intestinal system, the uterus and the larynx.

57. (Withdrawn) A method for applying non-excitatory stimuli to the heart and optionally performing pacing and defibrillation thereof, comprising providing a lead as claimed in any one of claims 1 to 44 and 46 to 47, and positioning said distal portion of the lead on the epicardium of said heart.

58. (Withdrawn) A method for applying non-excitatory stimuli to said tissue, comprising providing a lead as claimed in any one of claims 1 to 44 and 46 to 47, and positioning said distal portion of the lead on the epicardium of said heart.

59. (Withdrawn) A method according to claim 58, wherein said tissue is the cervix.

60. (Withdrawn) A method according to claim 58, wherein said tissue is the uterus.

61. (Withdrawn) A method according to claim 58, wherein said tissue is the urinary bladder.

62. (Canceled)

In re Application of: MALONEK et al.
Serial No.: 09/849,637
Filed: May 4, 2001
Office Action Mailing Date: July 9, 2007

Examiner: G.R. Evanisko
Group Art Unit: 3762
Attorney Docket: IMP031.228776

63. (Withdrawn) A lead according to claim 6, wherein the distance is about 5 mm.

64. (Withdrawn) A lead according to claim 15, wherein the longitudinal length is about 20 mm.

65. (Withdrawn) A lead according to claim 28, wherein the at least one implantable connector is an ISI connector.

66. (Withdrawn) A lead according to claim 30, wherein the bend comprises an angle of about 45° when unstressed.

67. (Withdrawn) A lead according to claim 70, comprising an external diameter such as to enable said to be introduced to its implantation site by passing through a lumen of diameter less than 1.5 mm.

68. (Withdrawn) A lead according to claim 70, comprising an external diameter such as to enable said lead to be introduced through the coronary sinus.

69. (Withdrawn) A lead according to claim 70, wherein one or more of the electrodes adapted for delivery and their associated one or more electrodes adapted for sensing may comprise a unitary electrode, said unitary electrode alternately used to sense activity of at least a portion of a tissue and provide a signal characteristic of said activity and to deliver a non-excitatory electric field to said at least portion of tissue to achieve a desired modification in the activity of said least a portion of a tissue.

In re Application of: MALONEK et al.
Serial No.: 09/849,637
Filed: May 4, 2001
Office Action Mailing Date: July 9, 2007

Examiner: G.R. Evanisko
Group Art Unit: 3762
Attorney Docket: IMP031.228776

70. (Withdrawn) A lead adapted for use in modifying the activity of at least a portion of human cardiac tissue, comprising an elongated lead body adapted for chronic implantation in contact with a beating human heart and having:

(i) a proximal end adapted for connection to a controller, and

(ii) a distal end flexible enough to be mounted on and conform to a cardiac chamber wall and comprising at least one signal delivery electrode,

wherein said delivery electrode:

(a) is adapted to withstand chronic delivery of an electric field having an amplitude suitable to modify the contractility of a human cardiac muscle when applied during a refractory period of said muscle, said field having a charge delivery duration of over 5 msec during a heart beat;

(b) has a capacitance of at least 300 microfarads; and

(c) has a diameter of less than 2.5mm.

71. (Withdrawn) A lead according to claim 70 further comprising at least one sensing electrode.

72. (Withdrawn) A lead according to claim 70, wherein said lead is flexible enough to pass through coronary veins past a coronary sinus.

73. (Withdrawn) A lead according to claim 70, wherein the signal delivery by the at least one signal delivery electrode has an energy of at least 100 microjoules.

74. (Previously Presented) A lead according to claim 43, wherein the distal end of said lead is flexible enough to be mounted on and conform to a cardiac chamber wall.

75. (Previously Presented) A lead according to claim 43, wherein the external diameter of said lead is smaller than the inner diameter of a human coronary sinus, thereby enabling said lead to pass through said coronary sinus.

76. (Previously Presented) A lead according to claim 43, wherein the external diameter of said lead is smaller than 1.5 mm.

77. (Currently Amended) A lead according to claim 43, wherein the external diameter of said ~~lead~~ signal deliver electrode is smaller than 1.2 mm.

78. (Previously Presented) A lead according to claim 43, wherein the external diameter and flexibility of said lead are suitable for insertion through the human coronary sinus reaching branches located on the left ventricle free wall.

79. (Canceled)

80. (Previously Presented) A lead according to claim 43, wherein the at least one signal delivery electrode is longer than the length of an implantable chronic pacing electrode and shorter than the length of an implantable defibrillation electrode.

81. (Canceled)

82. (Previously Presented) A lead according to claim 43, wherein the at least one signal delivery electrode is longer than 10 mm and shorter than 40 mm.

83. (Canceled)

84. (Previously Presented) A lead according to claim 43, wherein the at least one signal delivery electrode has impedance higher than 50 Ohm and lower than 500 Ohm.

85. (Canceled)

86. (Currently Amended) A lead according to claim 43, further comprising:

at least one sensing electrode flanking said at least one signal delivery electrode adapted for sensing the activity of said at least portion of a tissue and providing a signal characteristic of said activity; and

second ~~connection means~~connector operatively connected to said at least one sensing electrode for enabling said at least one sensing electrode to be operatively connected to a suitable ~~control means~~circuitry for determining a stimulus to be applied by said at least one signal delivery electrode.

87. (Previously Presented) A lead according to claim 43, wherein said at least one signal delivery electrode is made from titanium coated with titanium nitride.

88. (Previously Presented) A lead according to claim 43, wherein said at least one signal delivery electrode is made from platinum iridium coated with iridium oxide.

89. (Previously Presented) A lead according to claim 43, wherein said at least one signal delivery electrode is made from platinum iridium coated with titanium nitride.

90. (Previously Presented) A lead according to claim 43, wherein said at least one signal delivery electrode is made from platinum iridium coated with sintered platinum.

91. (Previously Presented) A lead according to claim 43, wherein said at least one signal delivery electrode is made from titanium.

92. (Previously Presented) A lead according to claim 43, wherein said at least one signal delivery electrode is made from platinum iridium.

93. (Previously Presented) A lead according to claim 43, wherein said at least one signal delivery electrode is made from pyrolitic carbon.

94. (Previously Presented) A lead according to claim 43, wherein said at least one signal delivery electrode is made from any conductive material approved for chronic use in the body.

95. (New) A lead according to claim 43, wherein the at least one signal delivery electrode is formed by a coil and wherein the coil is spirally wound around the lead.

96. (New) A lead according to claim 43, wherein the at least one signal delivery electrode is formed by a mesh of wires.

97. (New) A lead according to claim 86, wherein the at least one sensing electrode includes pairs of sensing electrodes.

In re Application of: MALONEK et al.
Serial No.: 09/849,637
Filed: May 4, 2001
Office Action Mailing Date: July 9, 2007

Examiner: G.R. Evanisko
Group Art Unit: 3762
Attorney Docket: IMP031.228776

98. (New) A lead according to claim 97, wherein a pair of sensing electrodes from the pairs of sensing electrodes is positioned on each side of the at least one signal delivery electrode.

99. (New) A lead according to claim 98, wherein the pairs of sensing electrodes are positioned on the lead in a position so that they can sense a local electrical activity of cardiac muscle under the at least one signal delivery electrode.

100. (New) A lead according to claim 43, wherein the lead includes a proximal end and a distal end with a tip, and wherein the tip of the distal end is a soft rounded tip.

101. (New) A lead according to claim 43 wherein the at least one signal delivery electrode is a plurality of signal delivery electrodes, and wherein the plurality of signal delivery electrodes are spaced along the lead such as to occupy a lead length of between about 20 mm and about 150 mm.

102. (New) A lead according to claim 101 wherein a distance between adjacent pairs of the electrodes is between about 5 mm to 30 mm.

103. (New) A lead according to claim 100 comprising a bend at the distal end, wherein the bend is at an angle between 30 degree to 90 degree.